

[COMMITTEE PRINT]

[SHOWING TEXT OF COMMITTEE PRINT AS APPROVED BY SUBCOMMITTEE
ON HEALTH ON JUNE 19, 2007]

110TH CONGRESS
1ST SESSION

H. R. _____

To amend the Federal Food, Drug, and Cosmetic Act with respect to pediatric
research improvement, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

M____ introduced the following bill; which was referred to the
Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with
respect to pediatric research improvement, and for other
purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Pediatric Research Eq-
5 uity Act of 2007”.

1 **SEC. 2. REAUTHORIZATION OF PEDIATRIC RESEARCH EQ-**
2 **UITY ACT.**

3 Section 505B of the Federal Food, Drug, and Cos-
4 metic Act (21 U.S.C. 355c) is amended to read as follows:

5 **“SEC. 505B. RESEARCH INTO PEDIATRIC USES FOR DRUGS**
6 **AND BIOLOGICAL PRODUCTS.**

7 “(a) NEW DRUGS AND BIOLOGICAL PRODUCTS.—

8 “(1) IN GENERAL.—A person that submits, on
9 or after the date of enactment of the Pediatric Re-
10 search Equity Act of 2007, an application (or sup-
11 plement to an application)—

12 “(A) under section 505 for a new active in-
13 gredient, new indication, new dosage form, new
14 dosing regimen, or new route of administration;
15 or

16 “(B) under section 351 of the Public
17 Health Service Act (42 U.S.C. 262) for a new
18 active ingredient, new indication, new dosage
19 form, new dosing regimen, or new route of ad-
20 ministration; shall submit with the application
21 the assessments described in paragraph (2).

22 “(2) ASSESSMENTS.—

23 “(A) IN GENERAL.—The assessments re-
24 ferred to in paragraph (1) shall contain data,
25 gathered using appropriate formulations for

1 each age group for which the assessment is re-
2 quired, that are adequate—

3 “(i) to assess the safety and effective-
4 ness of the drug or the biological product
5 for the claimed indications in all relevant
6 pediatric subpopulations; and

7 “(ii) to support dosing and adminis-
8 tration for each pediatric subpopulation for
9 which the drug or the biological product is
10 safe and effective.

11 “(B) SIMILAR COURSE OF DISEASE OR
12 SIMILAR EFFECT OF DRUG OR BIOLOGICAL
13 PRODUCT.—

14 “(i) IN GENERAL.—If the course of
15 the disease and the effects of the drug are
16 sufficiently similar in adults and pediatric
17 patients, the Secretary may conclude that
18 pediatric effectiveness can be extrapolated
19 from adequate and well-controlled studies
20 in adults, usually supplemented with other
21 information obtained in pediatric patients,
22 such as pharmacokinetic studies.

23 “(ii) EXTRAPOLATION BETWEEN AGE
24 GROUPS.—A study may not be needed in
25 each pediatric age group if data from one

1 age group can be extrapolated to another
2 age group.

3 “(iii) INFORMATION ON EXTRAPO-
4 LATION.—A brief documentation of the sci-
5 entific data supporting the conclusion
6 under clauses (i) and (ii) shall be included
7 in the medical review that is collected as
8 part of the application under section 505
9 of this Act or section 351 of the Public
10 Health Service Act (42 U.S.C. 262).

11 “(3) DEFERRAL.—

12 “(A) IN GENERAL.—On the initiative of
13 the Secretary or at the request of the applicant,
14 the Secretary may defer submission of some or
15 all assessments required under paragraph (1)
16 until a specified date after approval of the drug
17 or issuance of the license for a biological prod-
18 uct if—

19 “(i) the Secretary finds that—

20 “(I) the drug or biological prod-
21 uct is ready for approval for use in
22 adults before pediatric studies are
23 complete;

24 “(II) pediatric studies should be
25 delayed until additional safety or ef-

1 fectiveness data have been collected;
2 or

3 “(III) there is another appro-
4 priate reason for deferral; and

5 “(ii) the applicant submits to the Sec-
6 retary—

7 “(I) certification of the grounds
8 for deferring the assessments;

9 “(II) a description of the planned
10 or ongoing studies;

11 “(III) evidence that the studies
12 are being conducted or will be con-
13 ducted with due diligence and at the
14 earliest possible time; and

15 “(IV) a timeline for the comple-
16 tion of such studies.

17 “(B) ANNUAL REVIEW.—

18 “(i) IN GENERAL.—On an annual
19 basis following the approval of a deferral
20 under subparagraph (A), the applicant
21 shall submit to the Secretary the following
22 information:

23 “(I) Information detailing the
24 progress made in conducting pediatric
25 studies.

1 “(II) If no progress has been
2 made in conducting such studies, evi-
3 dence and documentation that such
4 studies will be conducted with due
5 diligence and at the earliest possible
6 time.

7 “(ii) PUBLIC AVAILABILITY.—The in-
8 formation submitted through the annual
9 review under clause (I) shall promptly be
10 made available to the public in an easily
11 accessible manner, including through the
12 website of the Food and Drug Administra-
13 tion.

14 “(4) WAIVERS.—

15 “(A) FULL WAIVER.—On the initiative of
16 the Secretary or at the request of an applicant,
17 the Secretary shall grant a full waiver, as ap-
18 propriate, of the requirement to submit assess-
19 ments for a drug or biological product under
20 this subsection if the applicant certifies and the
21 Secretary finds that—

22 “(i) necessary studies are impossible
23 or highly impracticable (because, for exam-
24 ple, the number of patients is so small or
25 the patients are geographically dispersed);

1 “(ii) there is evidence strongly sug-
2 gesting that the drug or biological product
3 would be ineffective or unsafe in all pedi-
4 atric age groups; or

5 “(iii) The drug or biological product—

6 “(I) does not represent a mean-
7 ingful therapeutic benefit over existing
8 therapies for pediatric patients; and

9 “(II) is not likely to be used in a
10 substantial number of pediatric pa-
11 tients.

12 “(B) PARTIAL WAIVER.—On the initiative
13 of the Secretary or at the request of an appli-
14 cant, the Secretary shall grant a partial waiver,
15 as appropriate, of the requirement to submit as-
16 sessments for a drug or biological product
17 under this subsection with respect to a specific
18 pediatric age group if the applicant certifies
19 and the secretary finds that—

20 “(i) necessary studies are impossible
21 or highly impracticable (because, for exam-
22 ple, the number of patients in that age
23 group is so small or patients in that age
24 group are geographically dispersed);

1 “(ii) there is evidence strongly sug-
2 gesting that the drug or biological product
3 would be ineffective or unsafe in that age
4 group;

5 “(iii) the drug or biological product—
6 “(I) does not represent a mean-
7 ingful therapeutic benefit over existing
8 therapies for pediatric patients in that
9 age group; and

10 “(II) is not likely to be used by
11 a substantial number of pediatric pa-
12 tients in that age group; or

13 “(iv) the applicant can demonstrate
14 that reasonable attempts to produce a pe-
15 diatric formulation necessary for that age
16 group have failed.

17 “(C) PEDIATRIC FORMULATION NOT POS-
18 SIBLE.—If a waiver is granted on the ground
19 that it is not possible to develop a pediatric for-
20 mulation, the waiver shall cover only the pedi-
21 atric groups requiring that formulation. An ap-
22 plicant seeking either a full or partial waiver
23 shall submit to the Secretary documentation de-
24 tailing why a pediatric formulation cannot be
25 developed and, if the waiver is granted, the ap-

1 plicant’s submission shall promptly be made
2 available to the public in an easily accessible
3 manner, including through posting on the
4 website of the Food and Drug Administration.

5 “(D) LABELING REQUIREMENT.—If the
6 Secretary grants a full or partial waiver because
7 there is evidence that a drug or biological prod-
8 uct would be ineffective or unsafe in pediatric
9 populations, the information shall be included
10 in the labeling for the drug or biological prod-
11 uct.

12 “(b) MARKETED DRUGS AND BIOLOGICAL PROD-
13 UCTS.—

14 “(1) IN GENERAL.—Beginning on the date of
15 enactment of the Pediatric Research Equity Act of
16 2007, after providing notice in the form of a letter
17 and an opportunity for written response and a meet-
18 ing, which may include an advisory committee meet-
19 ing, the Secretary may (by order in the form of a
20 letter) require the sponsor or holder of an approved
21 application for a drug under section 505 or the hold-
22 er of a license for a biological product under section
23 351 of the Public Health Service Act (42 U.S.C.
24 262) to submit by a specified date the assessments

1 described in subsection (a)(2), if the Secretary finds
2 that—

3 “(A)(i) the drug or biological product is
4 used for a substantial number of pediatric pa-
5 tients for the labeled indications; and

6 “(ii) adequate pediatric labeling could con-
7 fer a benefit on pediatric patients;

8 “(B) there is reason to believe that the
9 drug or biological product would represent a
10 meaningful therapeutic benefit over existing
11 therapies for pediatric patients for 1 or more of
12 the claimed indications; or

13 “(C) the absence of adequate pediatric la-
14 beling could pose a risk to pediatric patients.

15 “(2) WAIVERS.—

16 “(A) FULL WAIVER.—At the request of an
17 applicant, the Secretary shall grant a full waiv-
18 er, as appropriate, of the requirement to submit
19 assessments under this subsection if the appli-
20 cant certifies and the Secretary finds that—

21 “(i) necessary studies are impossible
22 or highly impracticable (because, for exam-
23 ple, the number of patients in that age
24 group is so small or patients in that age
25 group are geographically dispersed); or

1 “(ii) there is evidence strongly sug-
2 gesting that the drug or biological product
3 would be ineffective or unsafe in all pedi-
4 atric age groups.

5 “(B) PARTIAL WAIVER.—At the request of
6 an applicant, the Secretary shall grant a partial
7 waiver, as appropriate, of the requirement to
8 submit assessments under this subsection with
9 respect to a specific pediatric age group if the
10 applicant certifies and the Secretary finds
11 that—

12 “(i) necessary studies are impossible
13 or highly impracticable (because, for exam-
14 ple, the number of patients in that age
15 group is so small or patients in that age
16 group are geographically dispersed);

17 “(ii) there is evidence strongly sug-
18 gesting that the drug or biological product
19 would be ineffective or unsafe in that age
20 group;

21 “(iii)(I) the drug or biological prod-
22 uct—

23 “(aa) does not represent a mean-
24 ingful therapeutic benefit over existing

1 therapies for pediatric patients in that
2 age group; and

3 “(bb) is not likely to be used in
4 a substantial number of pediatric pa-
5 tients in that age group; and

6 “(II) the absence of adequate labeling
7 could not pose significant risks to pediatric
8 patients; or

9 “(iv) the applicant can demonstrate
10 that reasonable attempts to produce a pe-
11 diatric formulation necessary for that age
12 group have failed.

13 “(C) PEDIATRIC FORMULATION NOT POS-
14 SIBLE.—If a waiver is granted on the ground
15 that it is not possible to develop a pediatric for-
16 mulation, the waiver shall cover only the pedi-
17 atric groups requiring that formulation. An ap-
18 plicant seeking either a full or partial waiver
19 shall submit to the Secretary documentation de-
20 tailing why a pediatric formulation cannot be
21 developed and, if the waiver is granted, the ap-
22 plicant’s submission shall promptly be made
23 available to the public in an easily accessible
24 manner, including through posting on the
25 website of the Food and Drug Administration.

1 “(D) LABELING REQUIREMENT.—If the
2 Secretary grants a full or partial waiver because
3 there is evidence that a drug or biological prod-
4 uct would be ineffective or unsafe in pediatric
5 populations, the information shall be included
6 in the labeling for the drug or biological prod-
7 uct.

8 “(c) MEANINGFUL THERAPEUTIC BENEFIT.—For
9 the purposes of paragraph (4)(A)(iii)(I) and (4)(B)(iii)(I)
10 of subsection (a) and paragraphs (1)(B)(I) and
11 (2)(B)(iii)(I)(aa) of subsection (b), a drug or biological
12 product shall be considered to represent a meaningful
13 therapeutic benefit over existing therapies if the Secretary
14 determines that—

15 “(1) if approved, the drug or biological product
16 could represent an improvement in the treatment,
17 diagnosis, or prevention of a disease, compared with
18 marketed products adequately labeled for that use in
19 the relevant pediatric population; or

20 “(2) the drug or biological product is in a class
21 of products or for an indication for which there is
22 a need for additional options.

23 “(d) SUBMISSION OF ASSESSMENTS.—If a person
24 fails to submit an assessment described in subsection
25 (a)(2), or a request for approval of a pediatric formulation

1 described in subsection (a) or (b), in accordance with ap-
2 plicable provisions of subsections (a) and (b)—

3 “(1) the drug or biological product that is the
4 subject of the assessment or request may be consid-
5 ered misbranded solely because of that failure and
6 subject to relevant enforcement action (except that
7 the drug or biological product shall not be subject to
8 action under section 303); but

9 “(2) the failure to submit the assessment or re-
10 quest shall not be the basis for a proceeding—

11 “(A) to withdraw approval for a drug
12 under section 505(e); or

13 “(B) to revoke the license for a biological
14 product under section 351 of the Public Health
15 Service Act (42 U.S.C. 262).

16 “(e) MEETINGS.—Before and during the investiga-
17 tional process for a new drug or biological product, the
18 Secretary shall meet at appropriate times with the sponsor
19 of the new drug or biological product to discuss—

20 “(1) information that the sponsor submits on
21 plans and timelines for pediatric studies; or

22 “(2) any planned request by the sponsor for
23 waiver or deferral of pediatric studies.

24 “(f) REVIEW OF PEDIATRIC ASSESSMENTS, DEFER-
25 RALS, AND WAIVERS.—

1 “(1) REVIEW.—The Secretary shall utilize an
2 internal committee to review all determinations that
3 a pediatric assessment is required under this section
4 and all deferral and waiver requests made pursuant
5 to this section. Such internal committee shall in-
6 clude, as appropriate, employees of the Food and
7 Drug Administration, with expertise such as pedi-
8 atrics (including representation from the Office of Pe-
9 diatric Therapeutics), biopharmacology, statistics,
10 chemistry, legal issues, pediatric ethics, subject mat-
11 ter expertise pertaining to the pediatric product
12 under review, and other individuals as determined
13 appropriate by the Secretary.

14 “(2) ACTIVITY BY COMMITTEE.—The committee
15 referred to in paragraph (1) may operate using ap-
16 propriate members of such committee and need not
17 convene all members of the committee.

18 “(3) DOCUMENTATION OF COMMITTEE AC-
19 TION.—For each drug or biological product, the
20 committee referred to in paragraph (1) shall docu-
21 ment, for each activity described in paragraph (4),
22 which members of the committee participated in
23 such activity.

24 “(4) REVIEW OF REQUESTS FOR PEDIATRIC AS-
25 SESSMENTS, DEFERRALS AND WAIVERS.—All deter-

1 minations that a pediatric assessment required
2 under this section and all requests for deferrals and
3 waivers from the requirement to conduct a pediatric
4 assessment under this section shall be reviewed by
5 the committee referred to in paragraph (1).

6 “(5) TRACKING OF ASSESSMENTS AND LABEL-
7 ING CHANGES.—Beginning on the date of enactment
8 of the Pediatric Research Equity Act of 2007, the
9 Secretary shall track and make available to the pub-
10 lic in an easily accessible manner, including through
11 post on the website of the Food and Drug Adminis-
12 tration—

13 “(A) the number of assessments conducted
14 under this section;

15 “(B) the specific drugs and biological prod-
16 ucts and their uses assessed under this section;

17 “(C) the types of assessments conducted
18 under this section, including trial design, the
19 number of pediatric patients studied, and the
20 number of centers and countries involved;

21 “(D) the total number of deferrals re-
22 quested and granted under this section and, if
23 granted, the reasons for such deferrals, the
24 timeline for completion, and the number com-

1 pleted and pending by the specified date, as
2 outlined in subsection (a)(3);

3 “(E) the number of waivers requested and
4 granted under this section and, if granted, the
5 reasons for the waivers;

6 “(F) the number of pediatric formulations
7 developed and the number of pediatric formula-
8 tions not developed and the reasons any such
9 formulation were not developed;

10 “(G) the labeling changes made as a result
11 of assessments conducted under this section;

12 “(H) an annual summary of labeling
13 changes made as a result of assessments con-
14 ducted under this section for distribution pursu-
15 ant to subsection (h)(2); and

16 “(I) an annual summary of information
17 submitted pursuant to subsection (a)(3)(B).

18 “(6) COMMITTEE.—The committee established
19 under paragraph (1) is the committee established
20 under section 505A(f)(1).

21 “(g) LABELING CHANGES.—

22 “(1) PRIORITY STATUS FOR PEDIATRIC APPLI-
23 CATIONS.—Any supplement to an application under
24 section 505 and section 351 of the Public Health
25 Service Act proposing a labeling change as a result

1 of any pediatric assessments conducted pursuant to
2 this section—

3 “(A) shall be considered a priority applica-
4 tion or supplement; and

5 “(B) shall be subject to the performance
6 goals established by the Commissioner for pri-
7 ority drugs.

8 “(2) DISPUTE RESOLUTION.—

9 “(A) REQUEST FOR LABELING CHANGE
10 AND FAILURE TO AGREE.—If, on or after the
11 date of enactment of the Pediatric Research
12 Equity Act of 2007, the Commissioner deter-
13 mines that a sponsor and the Commissioner
14 have been unable to reach agreement on appro-
15 priate changes to the labeling for the drug that
16 is the subject of the application or supplement,
17 not later than 180 days after the date of the
18 submission of the application or supplement—

19 “(i) the Commissioner shall request
20 that the sponsor of the application make
21 any labeling change that the Commissioner
22 determines to be appropriate; and

23 “(ii) if the sponsor does not agree
24 within 30 days after the Commissioner’s
25 request to make a labeling change re-

1 requested by the Commissioner, the Commis-
2 sioner shall refer the matter to the Pedi-
3 atric Advisory Committee.

4 “(B) ACTION BY THE PEDIATRIC ADVISORY
5 COMMITTEE.—Not later than 90 days after re-
6 ceiving a referral under subparagraph (A)(ii),
7 the Pediatric Advisory Committee shall—

8 “(i) review the pediatric study reports;
9 and

10 “(ii) make a recommendation to the
11 Commissioner concerning appropriate la-
12 beling changes, if any.

13 “(C) CONSIDERATION OF RECOMMENDA-
14 TIONS.—The Commissioner shall consider the
15 recommendations of the Pediatric Advisory
16 Committee and, if appropriate, not later than
17 30 days after receiving the recommendation,
18 make a request to the sponsor of the applica-
19 tion to make any labeling changes that the
20 Commissioner determines to be appropriate.

21 “(D) MISBRANDING.—If the sponsor of the
22 application, within 30 days after receiving a re-
23 quest under subparagraph (c), does not agree to
24 make a labeling change requested by the Com-
25 missioner, the Commissioner may deem the

1 drug that is the subject of the application to be
2 misbranded.

3 “(E) NO EFFECT ON AUTHORITY.—Noth-
4 ing in this subsection limits the authority of the
5 United States to bring an enforcement action
6 under this Act when a drug lacks appropriate
7 pediatric labeling. Neither course of action (the
8 Pediatric Advisory Committee process or an en-
9 forcement action referred to in the preceding
10 sentence) shall preclude, delay, or serve as the
11 basis to stay the other course of action.

12 “(3) OTHER LABELING CHANGES.—If the Sec-
13 retary makes a determination that a pediatric as-
14 sessment conducted under this section does or does
15 not demonstrate that the drug that is the subject of
16 such assessment is safe and effective in pediatric
17 populations or subpopulations, including whether
18 such assessment results are inconclusive, the Sec-
19 retary shall order the label of such product to in-
20 clude information about the results of the assess-
21 ment and a statement of the Secretary’s determina-
22 tion.

23 “(h) DISSEMINATION OF PEDIATRIC INFORMA-
24 TION.—

1 “(1) IN GENERAL.—Not later than 180 days
2 after the date of submission of a pediatric assess-
3 ment under this section, the Secretary shall make
4 available to the public in an easily accessible manner
5 the medical, statistical, and clinical pharmacology re-
6 views of such pediatric assessments, and shall post
7 such assessments on the website of the Food and
8 Drug Administration.

9 “(2) DISSEMINATION OF INFORMATION RE-
10 GARDING LABELING CHANGES.—Beginning on the
11 date of enactment of the Pediatric Research Equity
12 Act of 2007, the Secretary shall require that the
13 sponsors of the assessments that result in labeling
14 changes that are reflected in the annual summary
15 developed pursuant to subsection (f)(5)(H) dis-
16 tribute such information to physicians and other
17 health care providers.

18 “(3) EFFECT OF SUBSECTION.—Nothing in this
19 subsection shall alter or amend Section 301(j) of
20 this Act or section 552 of title 5 or section 1905 of
21 title 18, United States Code.

22 “(i) ADVERSE EVENT REPORTING.—

23 “(1) REPORTING IN YEAR ONE.—Beginning on
24 the date of enactment of the Pediatric Research Eq-
25 uity Act of 2007, during the one-year period begin-

1 ning on the date a labeling change is made pursuant
2 to subsection (g), the Secretary shall ensure that all
3 adverse event reports that have been received for
4 such drug (regardless of when such report was re-
5 ceived) are referred to the Office of Pediatric Thera-
6 peutics. In considering the report, the Director of
7 such Office shall provide for the review of the report
8 by the Pediatric Advisory Committee, including ob-
9 taining any recommendations of such committee re-
10 garding whether the Secretary should take action
11 under this Act in response to such report.

12 “(2) REPORTING IN SUBSEQUENT YEARS.—Fol-
13 lowing the one-year period described in paragraph
14 (1), the Secretary shall, as appropriate, refer to the
15 Office of Pediatric Therapeutics all pediatric adverse
16 event reports for a drug for which a pediatric study
17 was conducted under this section. In considering the
18 report, the Director of such Office may provide for
19 the review of the report by the Pediatric Advisory
20 Committee, including obtaining any recommendation
21 of such Committee regarding whether the Secretary
22 should take action in response to such report.

23 “(3) EFFECT.—The requirements of this sub-
24 section shall supplement, not supplant, other review
25 of such adverse event reports by the Secretary.

1 “(j) SCOPE OF AUTHORITY.—Nothing in this section
2 provides to the Secretary any authority to require a pedi-
3 atric assessment of any drug or biological product, or any
4 assessment regarding other populations or uses of a drug
5 or biological product, other than the pediatric assessments
6 described in this section.

7 “(k) ORPHAN DRUGS.—Unless the Secretary re-
8 quires otherwise by regulation, this section does not apply
9 to any drug for an indication for which orphan designation
10 has been granted under section 526.

11 “(l) INSTITUTE OF MEDICINE STUDY.—

12 “(1) IN GENERAL.—Not later than three years
13 after the date of the enactment of the Pediatric Re-
14 search Equity Act of 2007, the Secretary shall con-
15 tract with the Institute of Medicine to conduct a
16 study and report to Congress regarding the pediatric
17 studies conducted pursuant to this section since
18 1997.

19 “(2) CONTENT OF STUDY.—The study under
20 paragraph (1) shall review and assess the use of ex-
21 trapolation for pediatric subpopulations, the use of
22 alternative endpoints for pediatric populations, neo-
23 natal assessment tools, the number and type of pedi-
24 atric adverse events, and ethical issues in pediatric
25 clinical trials.

1 “(3) REPRESENTATIVE SAMPLE.—The Institute
2 of Medicine may devise an appropriate mechanism to
3 review a representative sample of studies conducted
4 pursuant to this section from each review division
5 within the Center for Drug Evaluation and Research
6 in order to make the requested assessment.”.

7 **SEC. 3. GOVERNMENT ACCOUNTABILITY OFFICE REPORT.**

8 Not later than September 1, 2011, the Comptroller
9 General of the United States, in consultation with the Sec-
10 retary of Health and Human Services, shall submit to the
11 Congress a report that addresses the effectiveness of sec-
12 tions 505A and 505B of the Federal Food, Drug, and Cos-
13 metic Act (21 U.S.C. 355a) and section 409I of the Public
14 Health Service Act (42 U.S.C. 284m) in ensuring that
15 medicines used by children are tested and properly labeled.
16 Such report shall include—

17 (1) the number and importance of drugs and
18 biological products for children that are being tested
19 as a result of the amendments made by this Act and
20 the importance for children, health care providers,
21 parents, and others of labeling changes made as a
22 result of such testing;

23 (2) the number and importance of drugs and
24 biological products for children that are not being
25 tested for their use notwithstanding the provisions of

1 this Act and possible reasons for the lack of testing,
2 including whether the number of written requests
3 declined by sponsors or holders of drugs subject to
4 section 505A(g)(2) of the Federal Food, Drug, and
5 Cosmetic Act (21 U.S.C. 355a(g)(2)) has increased
6 or decreased as a result of the amendments made by
7 this Act;

8 (3) the number of drugs and biological products
9 for which testing is being done and labeling changes
10 required, including the date labeling changes are
11 made and which labeling changes required the use of
12 the dispute resolution process established pursuant
13 to the amendments made by this Act, together with
14 a description of the outcomes of such process, in-
15 cluding a description of the disputes and the rec-
16 ommendations of the Pediatric Advisory Committee;

17 (4) any recommendations for modifications to
18 the programs established under sections 505A and
19 505B of the Federal Food, Drug, and Cosmetic Act
20 (21 U.S.C. 355a) and section 409I of the Public
21 Health Service Act (42 U.S.C. 284m) that the Sec-
22 retary determines to be appropriate, including a de-
23 tailed rationale for each recommendation;

1 (5)(A) the efforts made by the Secretary to in-
2 crease the number of studies conducted in the
3 neonate population; and

4 (B) the results of those efforts, including efforts
5 made to encourage the conduct of appropriate stud-
6 ies in neonates by companies with products that
7 have sufficient safety and other information to make
8 the conduct of the studies ethical and safe; and

9 (6) pediatric studies conducted pursuant to this
10 section since 1997 and labeling changes made as a
11 result of such studies.